UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

PATRICIA STROMENGER,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

No. 3:12-cv-00686-HU

FINDINGS AND RECOMMENDATION

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HUBEL, J.,

In August 2006, Plaintiff Patricia Stromenger ("Stromenger") brought this products liability action in New Jersey state court, alleging that Defendant Novartis Pharmaceuticals Corporation's ("Novartis") prescription cancer drug Zometa caused her to develop osteonecrosis of the jaw ("ONJ"). Novartis timely removed the action to the United States District Court for the District of New Jersey based on federal question jurisdiction. The Judicial Panel on Multidistrict Litigation transferred the action under 28 U.S.C. § 1407 to the United States District Court for the Middle District of Tennessee (the "MDL court") and assigned it to Chief Judge Todd Campbell. Following discovery and briefing (but not resolution) of *Daubert* and dispositive motions in the MDL court, the case was remanded to the District of New Jersey before being transferred to this Court in April 2012. Novartis now moves for summary judgment on the ground that Plaintiff's suit is barred by the applicable statute of limitations. For the reasons set forth below, I recommend denying Novartis' motion (Docket No. 32) for summary judgment on this record.

I. FACTUAL AND PROCEDURAL BACKGROUND

The facts of this case are straightforward and largely undisputed. Stromenger is an 80-year-old Oregon resident who was diagnosed with breast cancer in November 2001. In January 2002, Stromenger's cancer metastasized to her bones and Stromenger's oncologist, Dr. Keith Lanier, prescribed a drug called Arimidex. Approximately one month later, the Food and Drug Administration ("FDA") approved the cancer drug Zometa as a safe and effective way

to treat bone metastases from solid tumors, and Zometa remains on the market today as an FDA-approved drug for that purpose.

In April 2002, Dr. Lanier began infusing Stromenger with Zometa, an intravenous bisphosphonate drug, on a monthly basis. In a progress note dated April 16, 2002, Dr. Lanier stated: "[Stromenger] will continue Arimidex and we will add Zometa for reduction of cancer-related bone events, for accelerated bone healing and for possible survival prolongation with this new bisphosphonate. This was reviewed with [Stromenger and her son] in detail." (Def.'s Mem. Supp. Ex. 19 at 4.)

In May 2002, after receiving a single dose of Zometa from Dr. Lanier, Stromenger's dentist, Dr. Barry Taylor, had to extract a root tip of tooth #28. The tooth had been previously extracted from Stromenger's right lower jaw.

In September 2002, Stromenger was referred to Dr. Eric Dierks, an oral surgeon at Columbia Otolaryngology Group Inc., in Portland, Oregon. Stromenger told Dr. Dierks she recently underwent a dental extraction and soon thereafter developed an infection, which did not clear up after treatment with antibiotics. Stromenger also reported being concerned with ongoing swelling and drainage of the right mandible. Dr. Dierks diagnosed Stromenger with acute osteomylitis of the jaw.

In August 2003, reports of ONJ in patients using bisphosphonates such as Zometa began to surface in medical literature. For example, in September 2003, the Journal of Oral and Maxillofacial Surgery published a "medical alert paper," which stated:

> Preliminary to a manuscript submitted to a refereed scientific journal, this preliminary communication is being issued by the Division of Oral and Maxillofacial Surgery at the University of Miami School of Medicine. It identifies 36 cases of painful bone exposure in the mandible, maxilla, or both, that were unresponsive to surgical or medical treatments. All patients were receiving pamidronate . . . or zoledronate (Zometa; Novartis Pharmaceuticals) therapy. It represents a heretofore unrecognized and unreported serious adverse affect; caution should be used when prescribing these drugs.

(Def.'s Mem. Supp. Ex. 11 at 2.)[1] That same month, Novartis submitted a label change for Zometa to the FDA. Specifically, Novartis added the following paragraph to the "Adverse Reactions" section of the package insert:

> Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa or other bisphosphonates, to concomitant drugs or other therapies (e.g., chemotherapy, radiotherapy, corticosteroid), to patient's underlying disease, or to other co-morbid risk factors (e.g., anemia, infection, pre-existing oral disease).

(Def.'s Mem. Supp. Ex 13 at 3.) This labeling revision was made available to the public in December 2003.

In January 2004, Dr. Dierks wrote in Stromenger's record: "I now think [Stromenger] is dealing with a Zometa related osteonecrosis [of the jaw] that has become secondarily infected." (Pl.'s Resp. Ex. 1.) The record is silent regarding discussions Dr. Dierks had at this time with Stromenger.

Novartis updated the Zometa label once again in February 2004, stating:

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[1] On this record, it appears that Novartis argues Stromenger's injury occurred in May 2002, despite the fact that reports of ONJ in patients using bisphosphonates did not surface in the medical literature until August 2003.

> Osteonecrosis of the jaw (ONJ) has been reported in patients with cancer receiving treatment regimens including bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. Many had signs of local infection including osteomyelitis.
>
> A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g., cancer, chemotherapy, corticosteroids, poor oral hygiene).
>
> While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/ risk assessment.

(Def.'s Mem. Supp. Ex. 16 at 12.)[2]

Based on Dr. Dierks' recommendation, Dr. Lanier decided to discontinue Stromenger's monthly dose of Zometa in March 2004. At that time, however, Stromenger states she was not aware that "Zometa was causing osteonecrosis of [her] jaw." (Stromenger Aff. ¶ 4.) Rather, Stromenger believed her "jaw problem was infection-related and that [she] needed the Zometa holiday and surgery to allow [her] to heal." (Stromenger Aff. ¶ 4.) The record is again silent with respect to what Dr. Dierks or Dr. Lanier explicitly told Stromenger in March 2004 as to exactly why she was no longer receiving Zometa.

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[2] I note the first paragraph suggests Novartis distinguished in 2004 between ONJ and osteomyelitis. Novartis also sent a "Dear Doctor" letter to hermatologists, urologists, oral surgeons, and oncologists in September 2004, which recited its September 2003 label change and February 2004 update.

In April 2004, Stromenger's gums had been eaten away to the point that bone in her right mandible was exposed. That same month, Dr. Dierks removed the sequestrum (the piece of dead bone separated from the sound bone during the process of necrosis) in Stromenger's jaw. According to the American Association of Oral and Maxillofacial Surgeons ("AAOMS"), patients may be considered to have BRONJ if the following three characteristics are present: (1) current and/or previous treatment with a bisphosphonate such as Zometa; (2) exposed bone in the maxillofacial region that has persisted for more than eight weeks; and (3) no history of radiation therapy to the jaw. (Def.'s Reply Ex. 1 at 3.) Stromenger's counsel claims that Dr. Dierks testified that Stromenger did not have exposed bone until sometime in April 2004. Although that testimony was not provided to the Court, in her affidavit Stromenger stated: "I did not know I had exposed bone until April of 2004[.]" (Stromenger Aff. ¶ 4.)

In May 2004, Dr. Dierks discussed with Stromenger his "hope that now that the necrotic bone had been cleanly removed [via the April 2004 debridement] that she would go on to complete healing." (Pl.'s Resp. Ex. 2.)

In June 2004, Stromenger and Dr. Lanier discussed "further bisphosphonate therapy." (Pl.'s Resp. Ex. 3.) However, Dr. Lanier informed Stromenger they "needed to wait until she was completely healed and at that point would reconsider reinstitution of bisphosphonate[s] . . . on a quarterly basis." (Pl.'s Resp. Ex. 3.)

In September 2004, Stromenger and Dr. Dierks "discussed the fact that Zometa related osteonecrosis has no known cure and the timeline for its resolution is also unknown." (Pl.'s Resp. Ex. 6.)

During a November 2004 consultation with Dr. Lanier, Stromenger asked "[a] number of questions . . . regarding bisphosphonate osteonecrosis." (Pl.'s Resp. Ex. 6.)

In January 2006, Stromenger saw a television commercial discussing lawsuits filed by individuals who allegedly developed BRONJ as a result of taking Zometa. Because "[t]his was the first time she suspected that there was something wrong with the drug that was connected to [her] condition," Stromenger "called her family lawyer about it and he referred her to the lawyers who filed this lawsuit." (Stromenger Aff. ¶ 8.)

On August 29, 2006, Stromenger commenced this case against Novartis, alleging that Zometa caused her to develop ONJ. Her complaint in this action pleads claims for compensatory damages under the theories of: (1) defective design (Count I), (2) failure to warn (Count II), (3) breach of implied warranty (Count III), (4) negligence (Count IV), and (5) violations of the New Jersey Consumer Fraud Act ("NJCFA") (Count V). Stromenger also pleads a claim for punitive damages under the New Jersey Punitive Damages Act ("NJCFA").

II. LEGAL STANDARD

Summary judgment is appropriate "if pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c). Summary judgment is not proper if factual issues exist

for trial. *Warren v. City of Carlsbad*, 58 F.3d 439, 441 (9th Cir. 1995).

The moving party has the burden of establishing the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party shows the absence of a genuine issue of material fact, the nonmoving party must go beyond the pleadings and identify facts which show a genuine issue for trial. *Id.* at 324. A nonmoving party cannot defeat summary judgment by relying on the allegations in the complaint, or with unsupported conjecture or conclusory statements. *Hernandez v. Spacelabs Medical, Inc.*, 343 F.3d 1107, 1112 (9th Cir. 2003). Thus, summary judgment should be entered against "a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322.

The court must view the evidence in the light most favorable to the nonmoving party. *Bell v. Cameron Meadows Land Co.*, 669 F.2d 1278, 1284 (9th Cir. 1982). All reasonable doubt as to the existence of a genuine issue of fact should be resolved against the moving party. *Hector v. Wiens*, 533 F.2d 429, 432 (9th Cir. 1976). Where different ultimate inferences may be drawn, summary judgment is inappropriate. *Sankovick v. Life Ins. Co. of N. Am.*, 638 F.2d 136, 140 (9th Cir. 1981).

However, deference to the nonmoving party has limits. The nonmoving party must set forth "specific facts showing a genuine issue for trial." FED. R. CIV. P. 56(e). The "mere existence of a scintilla of evidence in support of plaintiff's positions [is] insufficient." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252

(1986). Therefore, where "the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (internal quotation marks omitted).

III. DISCUSSION

The sole question presented in this motion is whether Stromenger's product liability claims are time-barred by the applicable statute of limitations. The parties agree that Oregon law applies to Stromenger's substantive causes of action.

Under Oregon law, a product liability action is defined as "a civil action brought against a manufacturer, distributer, seller or lessor of a product for damages arising out of: (1) [a]ny design, inspection, testing, manufacturing or other defect in a product; (2) [a]ny failure to warn regarding a product; or (3) [a]ny failure to properly instruct in the use of a product." OR. REV. STAT. 30.900(1)-(3). ORS 30.900 "embraces all theories a plaintiff can claim in an action based on a product defect," *Kambury v. DaimlerChrysler Corp.*, 185 Or. App. 635, 639 (2003), including, but not limited to, claims based on theories of negligence, strict liability, breach of warranty, and fraudulent misrepresentation. *Simonsen v. Ford Motor Co.*, 196 Or. App. 460, 466 (2005).

The limitations period for bringing product liability claims is set forth in ORS 30.905(2). The parties agree that all of Stromenger's substantive claims are subject to the two-year limitation period set forth in this statute. Prior to changes made by the 2003 Legislative Assembly, which took effect on January 1, 2004, the two-year limitation period began to run when the "death,

injury or damage complained of" occurred, regardless of whether the plaintiff discovered the harm within that two-year period. *Gladhart v. Oregon Vineyard Supply Co.*, 332 Or. 226, 234 (2001) (internal quotation marks omitted). Under the current version of ORS 30.905(2), "the statute of limitations for a product liability civil action for personal injury or property damage begins to run when the plaintiff first discovers or, in the exercise of reasonable care, should have discovered that the injury or other damage complained of exists and was the result of a product defect." *Fox v. Collins*, 213 Or. App. 451, 453 (2007).

In determining whether the pre-2004 or post-2004 version of the statute applies, the Court must examine whether the injury occurred before or after January 1, 2004. *See In re Zyprexa Prods. Liab. Litig.*, 727 F. Supp. 2d 101, 113 (E.D.N.Y. 2010) (explaining that "the amendments to ORS 30.905 by Section 1 of this 2003 act apply only to deaths, personal injuries or property damage that occurs on or after the effective date of this 2003 act [i.e., January 1, 2004]." (quoting 2003 Or. Laws. ch. 768 § 2(1) (H.B. 2080))). The parties here dispute (1) which version of ORS 30.905(2) applies to Stromenger's claims; and (2) when Stromenger actually discovered, or reasonably should have discovered, that her injury was the result of Zometa therapy.

Novartis' argument regarding the timeliness of Stromenger's product liability action is twofold. First, with respect to the pre-2004 version of ORS 30.905(2), Novartis argues that Stromenger's suit is untimely because it was not filed within two years of Stromenger's May 22, 2002 root tip extraction, which, in Novartis' view, should have started the running of the then-

applicable Oregon statute of limitations. Second, Novartis argues that, even assuming that the post-2004 version of ORS 30.905(2) applies, Stromenger's claims are untimely because she did not file her suit by April 2006, two years after Dr. Dierks first noted the existence of exposed bone in Stromenger's mouth.

Novartis' arguments miss the mark. With respect to the pre-2004 version of ORS 30.905, Novartis relies exclusively on a 3-page excerpt of Dr. Richard Kraut's deposition testimony, wherein he stated:

> Q: Turning back to your report which is Exhibit 5. On the final page of the report you wrote 'It is my considered opinion that Ms. Patricia Stromenger developed bisphosphonate-related jaw necrosis of her right mandible.' Do you hold that opinion to a reasonable degree of medical and scientific certainty?
>
> A. Yes.
>
> Q. In stating that she had bisphosphonate-related jaw necrosis are you following the AAOMS definition?
>
> A. Yes.
>
> Q. At what point do you believe her bisphosphonate-related jaw necrosis began?
>
> A. Well, she has a root taken out of tooth number 28 on May 22, 2002, and that's the right mandible and that never really goes on to heal and actually develops into full-blown bisphosphonate jaw necrosis resulting in a mandibular reception, a fibular reconstruction that's since had its problems.
>
> So I guess I would say that the triggering event here is the extraction of that tooth, and then since it never heals I don't know whether you want to wait eight weeks after the extraction and then say its bisphosphonate necrosis, or whether you want to say the bisphosphonate necrosis problems started the day the tooth was taken out, I don't think that's particularly critical, but we can discuss it if you wish.
>
> Q. If I understand . . . your discussion of the eight weeks, part of course of the AAOMS definition is that there be exposed bone for eight weeks, correct?
>
> A. Yeah, that's one of the key elements.

> Q. So in order to diagnose ONJ you need to have seen it for eight weeks, the exposed bone?
>
> A. Okay, yes.

(Kraut Dep. 36:8-37:24, Oct. 11, 2011.)

In the Court's view, and contrary to Novartis' characterization, a reasonable juror could understand Dr. Kraut's testimony to be that he believes the May 22, 2002 root tip extraction was the "triggering event" (i.e., an occurrence that begins a chain of events leading to other events) that caused Stromenger to "develop[] . . . full-blown bisphosphonate jaw necrosis." That does not mean, however, that this "triggering event" was an injury due to her Zometa use in May 2002 which she had only received once by that date. As Novartis' counsel informed the Court during oral argument, there are other factors at play:

> [MR. CHERNACK:] . . . [N]ow, osteomyelitis, just as a way of background, is an infection of the bone. In this case, the jaw bone. And what has been a debate in many of these cases is whether or not the osteomyelitis preceded or post-dated the presence of necrotic bone in the jaw.
>
> Plaintiffs will argue in almost all of these cases that what was called osteomyelitis was actually osteonecrosis due to the bisphosphonates that became secondarily infected. Meaning there was already dead bone and an infection came in.
>
> THE COURT: If there wasn't a statute of limitations issue or if we were beyond it in the case, what would Novartis' position be with respect to the causation of her problems with the jaw.
>
> MR. CHERNACK: Novartis' position would be that there's -- the more likely explanation is that it's infectious in origin [i.e., osteomyelitis-related].
>
> THE COURT: Infectious apart from Zometa?
>
> MR. CHERNACK: Correct. This is a woman who had severe dental problems. In fact, [she] had no remaining teeth at the time she began her treatment with Zometa. There's plenty [of] signs of infection. And while it is

> not possible to completely rule out the possibility of Zometa playing a role, the more likely explanation is that it is infectious in origin.

(Mot. Summ. J. Hr'g Tr. 7-8, Aug. 10, 2012.)

The problem this raises is when does the Zometa-related disease, "injury", start? It appears that there is in these cases a theme of which comes first, osteomyelitis or osteonecrosis. The record on this motion does not unequivocally answer that question. It remains for the jury to decide. In addition, as discussed at oral argument, Stromenger went on to develop full-blown stage three bisphosphonate necrosis sometime in 2004. The record is not clear what date in 2004 that occurred, nor is there anything in the record to even suggest when stage 1 or stage 2 osteonecrosis began.

Novartis relies on the testimony of Dr. Kraut to eliminate any question of fact about when osteonecrosis or Zometa-related injury occurred. It is insufficient for that purpose. The doctor is discussing a portion of the diagnostic criteria for bisphosphonate-related osteonecrosis when he touches on exposed bone in the jaw for 8 weeks. The doctor also discusses the root tip extraction as the event that began a series of events that ends with the Zometa related injury in his opinion. He dates the triggering event, and then there is loose testimony about tacking on 8 weeks for bone to be exposed after that May 2002 root tip extraction. The missing link in the record is evidence there was 8 weeks or any number of weeks of exposed bone in Stromenger's jaw.

In Novartis' reply in support of its motion, it attaches Exhibit 2, a deposition excerpt of Dr. Dierks. At page 24 he testifies that when he removed the necrotic bone (the sequestrum)

on April 29, 2004, there had not been exposed bone for more than 8 weeks. Exhibit 2, Dr. Dierks deposition, page 24.

Further, there is the statement by Dr. Kraut that he did not think the discussion in his deposition at pages 36 and 37 that Novartis relies on was "particularly critical". Despite his offer to discuss that with counsel, if there was such discussion with Dr. Kraut, it did not make it into this record on summary judgment leaving us to guess what he meant. The doctor could mean the discussion of when the bisphosphonate necrosis started is not critical in a medical sense or a legal sense at a minimum. One might expect he was not referring to the legal sense, since he is medically trained, not legally trained one presumes, which of course is where Novartis wants to take the analysis. It may not be critical from a medical standpoint as he was neither a treating physician, nor would when the disease started have any apparent significance in its treatment absent something in the record to suggest it was. This testimony is open to interpretation by the fact finder as to whether the doctor ever expressed an opinion to a reasonable medical probability when Stromenger's Zometa-related injury, osteonecrosis, not a root tip extraction or osteomyelitis, began.

It is also curious to note that, after considering other disease entities that might cause ONJ, such as Stromenger's original diagnosis of osteomyelitis, Dr. Kraut "concluded that Dr. Dierks [wa]s correct in his diagnosis of bisphosphonate-related jaw necrosis of the right mandible." (Def.'s Mem. Supp. Ex. 23 at 5.) Yet, the parties seem to concede that, at least on this record, Stromenger did not have exposed bone -- one of the defining

characteristics, or "key elements," of bisphosphonate-related ONJ -- until April 2004. When she accumulated 8 weeks with exposed bone is not established on this record. Nor is the date when bone was first exposed as the beginnings of osteonecrosis.

For all these reasons, there is a question of fact regarding when Stromenger's alleged Zometa-related injury began precluding a grant of summary judgment for Novartis on the basis that it began before January 1, 2004, when the discovery rule gloss to the product liability statute of limitations in Oregon was effective.

There is also an issue of fact as to when Stromenger first discovered or, in the exercise of reasonable care, should have discovered the injury or other damage she alleges and that it was the result of a product defect. *Collins*, 213 Or. App. at 453. Originally, Stromenger was diagnosed with an infection; however, in January 2004, Dr. Dierks diagnosed Stromenger "with . . . Zometa related osteonecrosis [of the jaw] that has become secondarily infected." (Pl.'s Resp. Ex. 1.) This was the first time one of Stromenger's treating physicians rendered such an opinion as to her condition. With this in mind, there is evidence from which a reasonable jury could decide that the filing of Stromenger's claim is timely under the post-2004 version of ORS 30.905(2).

For example, in March 2004, based on Dr. Dierk's recommendation, Dr. Lanier decided to discontinue Stromenger's monthly dose of Zometa. At that time, Stromenger claims she still held the belief that her problem was infection-related (a belief Novartis holds as well). The chart note provided by Dr. Lanier's clinic on March 9, 2004, the day Stromenger was informed that she would not receive her Zometa dose, does not eliminate this

uncertainty: "After assessment, they want to hold Zometa until further information. The patient has been having some pain in her jaw and *sometimes* osteonecrosis can occur related to Zometa therapy. This was recommended by another physician who has seen the patient about this pain." (Def.'s Mem. Supp. Ex. 21 at 3) (emphasis added). In fact, the only definitive evidence on this record of a doctor explicitly discussing Zometa-related osteonecrosis with Stromenger occurred on September 2, 2004: "Pat and I also discussed the fact that Zometa related osteonecrosis has no known cure and the time line for its resolution is also unknown." (Pl.'s Resp. Ex. 6.) Viewing this evidence in the light most favorable to Stromenger, her filing of the Complaint could be found timely by the jury.

IV. CONCLUSION

For the reasons set forth above, Novartis' motion (Docket No. 32) for summary judgment should be DENIED.

V. SCHEDULING ORDER

The Findings and Recommendation will be referred to a district judge. Objections, if any, are due **November 13, 2012.** If no objections are filed, then the Findings and Recommendation will go under advisement on that date. If objections are filed, then a response is due **November 30, 2012.** When the response is due or filed, whichever date is earlier, the Findings and Recommendation will go under advisement.

Dated this 22nd day of October, 2012.

/s/ Dennis J. Hubel

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Dennis J. Hubel

United States Magistrate Judge